

Attachment 1 – Comments on “Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Time Stamps” Draft Guidance. Docket No. 00D-1542

1. Purpose

No comments.

2. Scope

- a. The second paragraph makes use of the term “key” validation principles. Recommend that the term “fundamental” be used instead. The implication here is that these are basic requirements upon which further layers can be added as appropriate. Given the context within which this guide is written, this term better fits the requirement.

2.1 Applicability

No comments.

2.2 Audience

- a. People are only subject to Part 11 as a result of the data and records they create or control. Recommend rewording the first bullet as “Persons responsible for the management and control of records subject to Part 11.”
- b. To include individuals making changes to existing products, reword the third bullet as “Persons who develop or modify products or provide services to enable the implementation of Part 11 requirements.”
- c. Reword the final sentence as “This draft guidance may also assist FDA staff who apply Part 11 to processes, procedures, operations and systems subject to the regulation.”
- d. For the sake of clarity, it would be useful to provide a list of examples of the ‘persons’ being referred to in this section. (e.g. users, DBAs, developers, ...)

3. Definitions and Terminology

No comments.

4. Regulatory Requirements; What Does Part 11 Require?

No comments.

5. Key Principles and Practices

No comments.

5.1 Time Stamp Accuracy

- a. For computers that are not connected to a network, would it be appropriate to have a manual process of verification of time in place?
- b. What is the definition of periodically – if a clinical study is six months long how often should verification be done? Daily, weekly, monthly?

- c. In the laptop discussion, should a difference be made in browser technology versus client server or others where data is saved on the laptop and at a later time uploaded to the server?
- d. For browser technology, is it the server time that is needed in the audit trail?
- e. We are suggesting to reword the final sentence as, "It is extremely important for time stamps to be based upon computer systems that are of known and justifiable accuracy and reliability. By adding this emphasis, this means that the organization implementing the system will determine and justify this information in relation to the process being controlled."
- f. Needs clarity regarding whether it means that the recognized standard computer clock used to synchronize the network "master clock" or time server is site specific, time zone specific or country specific.

5.2 Systems Clock Security

No comments.

5.3 Time Zones

- a. Clarification is needed around the "signer's local time is the one to be recorded..." (i.e., if one sends information after being signed in PST to EST one hour later, which time is the valid time with that record?)

5.4 Expression of Date and Time

No comments.

5.5 Precision of Date and Time Expressions

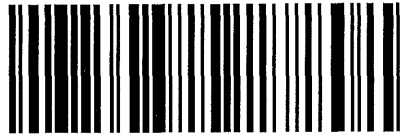
No comments.

6. Other Uses of Time Stamps in Electronic Recordkeeping

No comments.

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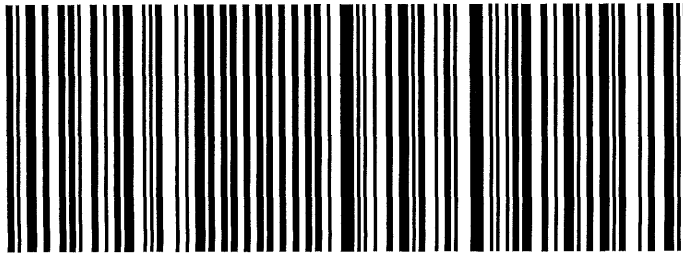
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